Remarks

The Examiner has stated that claims 9-11 and 19-22 are withdrawn from consideration as being drawn to nonelected inventions. However, Applicant clearly and properly elected the Examiner's "Group 1" claims set forth in the March 16, 2007 restriction requirement, which included claims 1-18. The exclusion of claims 9-11 is unexplained and improper; examination and allowance of claims 9-11 is respectfully requested. Applicants additionally request that any rejection of claims 9-11 be made NON-FINAL.

The Examiner has rejected claims 1-6 and 12-18 as anticipated by U.S. Patent No. 5,443,981 to Belanger and claims 1-4, 7, 8, 12, and 18 as anticipated by U.S. Publ. No. 2005/0069505 to Breton et al. The Examiner has relied on U.S. Patent No. 6,372,446 to Miller in both cases as supplying the reference to chitin.

The Examiner has also rejected claims 1-8 and 12-18 as obvious over Belanger in light of U.S. Patent No. 6,221,378 to Modi and claims 1-4, 7, 8, and 12-18 as obvious over Breton in light of Modi. Again the Examiner relies on the Miller reference to argue that the presence of chitin is inherent.

Please note that the hyperlink embedded in the specification has been deleted to overcome the Examiner's objection, and claims 7 and 10 have been amended to correct typographical errors.

I. Withdrawal of Claims 9-11

As noted above, Applicant clearly and properly elected the Examiner's "Group 1" claims set forth in the March 16, 2007 restriction requirement, which included claims 1-18. Applicant also elected *Ascomycotina* per the Examiner's election of species requirement. However, yeast is a subset of *Ascomycotina*, *Saccharomyces cerevisiae* is a specific type of yeast, and the presence

of chitin and/or chitosan is not related to the election of *Ascomycotina*. As a result, each of claims 1-18 reads on the elected species, and each of claims 1-18 should be examined. Such action is respectfully but vigorously requested. In addition, any rejection of claims 9-11 should be made NON-FINAL.

II. Rejection of Claims 1-6 and 12-18 under 35 U.S.C. § 102

The Examiner has rejected claims 1-6 and 12-18 as anticipated by U.S. Patent No. 5,443,981 to Belanger. The Examiner argues that the disclosed fungus, *Acremonium typhinum* (At) is the claimed pharmaceutically active compound. See 6/22/7 OA, p. 3, "the fraction [of At] is reactive with BCA (pharmaceutically active compound...)." However, the Belanger reference does not anticipate claim 1, or any of the claims dependent thereon, because the Belanger reference does not disclose a composition comprising a pharmaceutically active compound and a non-encapsulating fungal adjuvant.

Belanger discloses an endophytic turfgrass fungus, *Acremonium typhinum* (At), that is known to confer protection from insects to the grasses it infects. A membrane fraction of At has endoproteolytic activity and is reactive with BCA. In other words, the At membrane fraction is able to break down protein molecules and contains peptides. The Belanger reference notes that the particular endophytes are effective in specific host species but not others, and that the interaction that makes endophytes effective in some hosts but not others is "completely unknown." Col. 1, lines 55-57.

The Belanger reference is specifically directed to extracting and isolating elements of At that, due to the presence of proteolytic activity, appear to have some functionality and therefore some research value. Once identified and extracted, these elements can be used to further examine and research the nature of the relationship between the At endophyte and the grasses to

which it imparts insect resistance. However, Belanger does not suggest that the At membrane fraction is the active element in insect deterrence or that it has other pharmaceutical properties. Thus, Belanger fails to teach an element of the claimed invention, a pharmaceutically active compound.

Further, even if the At fragment were considered pharmaceutically active, Belanger does not teach a fungal adjuvant to the fragment. The At fragment is, itself, a fungal fragment; no other adjuvant, fungal or otherwise, is disclosed. The Examiner notes that At fragment activity is inhibited by PMSF, perhaps suggesting that PMSF is the adjuvant. However, claim 1 specifically requires that the adjuvant be a *fungal cell or fragment thereof*, which PMSF is not. As a result, Belanger satisfies neither of the requirements of claim 1 as originally submitted.

For the reasons above, the Belanger reference cannot be considered anticipatory. Withdrawal of the § 102 rejection on the basis of Belanger is therefore required.

III. Rejection of Claims 1-4, 7-8, 12, and 18 under 35 U.S.C. § 102

The Examiner has rejected claims 1-4, 7, 8, 12, and 18 as anticipated by U.S. Publ. No. 2005/0069505 to Breton et al. The Examiner argues that yeast extract, which contains a fungal cell or fragment, is a non-encapsulating adjuvant within the meaning of the claims. See 6/22/7 OA, p. 5, "the yeast extract (contains a fungal cell or fragment)..." However, the mere disclosure of yeast extract does not rise to the disclosure of "a non-encapsulating adjuvant, wherein the adjuvant comprises a fungal cell or a fragment thereof" as required by claim 1.

Breton discloses a combination of a lactic acid bacteria and a carotenoid as a compound conferring photoprotective properties. Oral administration of the combination requires a carrier, and Breton discloses the use of various carriers including food, pharmaceutical products, or nutritional supplements. See ¶ 26. Breton provides a number of examples in which the carrier is

maltodextrin powder. See p. 3, examples 1-3. Breton also provides examples in which the carrier further includes 75 mg of lyophilized *S. cerevisae* (Baker's yeast). See p. 3, examples 4-6.

Claim 1 requires an adjuvant and further requires that the adjuvant comprise a fungal cell or fungal cell fragment. Breton does not disclose the use of a fungal cell or fragment thereof necessarily would act as an adjuvant to the pharmaceutically active compound. An adjuvant must, by definition, act to increase or aid the effect of that to which it is added.[1] The Baker's yeast is used only as an optional nutritional additive to the carrier, not as its adjuvant. Because the Breton reference does not disclose an adjuvant, either expressly or under the principals of inherency, the § 102 rejection must be withdrawn for claim 1 and all remaining pending claims, each of which is dependent either directly or indirectly on claim 1.

IV. Rejection of Claims 1-8 and 12-18 under 35 U.S.C. § 103

The Examiner has rejected claims 1-8 and 12-18 as obvious over Belanger in light of U.S. Patent No. 6,221,378 to Modi. The application of the Modi reference to the Belanger reference does not cure the failure of Belanger to disclose either a pharmaceutically active compound or a non-encapsulating fungal adjuvant, and even if it did, one of ordinary skill in the art would not have been motivated to combine these to produce the invention. The combination does not obviate claim 1 and the § 103 rejection should be withdrawn.

Modi discloses a micellar delivery system for pharmaceutically active compounds. Specifically, a pharmaceutical drug, which typically comprise large molecules, is encapsulated in micelles. Micelles are believed to (1) encapsulate the drug molecules efficiently and (2) due to their small size, carry drug molecules across mucous membranes efficiently. Modi does not

[1] adjuvant: A pharmacological agent added to a drug to increase or aid its effect. The American Heritage® Dictionary of the English Language: Fourth Edition, 2000.

disclose the use of a fungal cell or fragment thereof as an adjuvant. In fact, Modi discusses various "enhancers" that facilitate the absorption or transport of large molecules across membranes (see col. 2, lines 4-12) but does not list any fungal species.

The Modi reference does not cure the failures of the Belanger reference because even combined, there is no suggestion that a fungal cell or a fragment thereof could be used as an adjuvant to a pharmaceutically active compound. Further, even if the combination did obviate the present invention, which it unquestionably does not, there is no motivation to combine Belanger, which is directed to isolating active compounds of an endophytic fungus of turfgrasses, and Modi, which is directed to a micellar drug delivery system, to produce the claimed invention. As a result, the § 103 rejection based on the Belanger and Modi references must be withdrawn.

V. Rejection of Claims 1-4, 7-8, and 12-18 under 35 U.S.C. § 103

The Examiner has rejected claims 1-4, 7, 8, and 12-18 as obvious over Breton in light of Modi. As with the previous § 103 rejection, the application of the Modi reference to the Breton reference does not cure the failure of Breton to employ a fungal adjuvant, and even if it did, there is no reason one skilled in the art would consider combining the references. The combination does not obviate claim 1 and the § 103 rejection should be withdrawn.

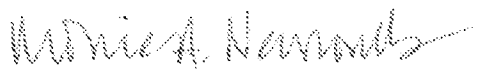
The Modi reference does not cure the failures of Breton because even combined, there is no suggestion that a fungal cell or a fragment thereof could be used as an adjuvant to a pharmaceutically active compound. Further, even if the combination did obviate the present invention, which it unquestionably does not, there is no motivation to combine Breton, which is directed to orally administered photoprotective compounds, and Modi, which is directed to a

micellar drug delivery system, to produce the claimed invention. As a result, the § 103 rejection based on the Breton and Modi references must be withdrawn.

VI. Conclusion

It is submitted that each of claims 1-18 is pending and is in compliance with 35 U.S.C. §§ 102 and 103. Applicant hereby requests a three-month extension of time for reply. Authorization is hereby given to charge Deposit Account No. 50-1170 in the amount of $1,050 for the fee associated with such an extension for a large entity. No additional fees are believed to be due with the submission of this communication. Nevertheless, the Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170. The Examiner is encouraged to contact the undersigned by phone if questions remain after consideration of this response, or if such would otherwise facilitate prosecution.

Respectfully submitted,



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